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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,070	07/18/2001	Dachuan Yang	S63.2-9826	7520

490 7590 04/04/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/908,070	YANG ET AL.	
	Examiner	Art Unit	
	Gwen Phanijphand	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/31/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-14 is/are allowed.
- 6) ☒ Claim(s) 15-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

RESPONSE TO AMENDMENT

Applicant amended claim 16. However, claim "15" is listed as the amended claim on page 2 of the amendment. Examiner has changed "15" to "16" to correct the amended claim number on page 2.

Claim Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 15-18 and 31-38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,254,634 to Anderson et al.

Regarding claim 15, Anderson et al. disclose a method that can detect lubricous coating on a medical device by providing a fluorescent lubricant wherein the lubricant comprises fluorescent groups on the lubricant molecules. Anderson et al. disclose an intermediate layer, which is "abrasion resistant" (col. 5, ll. 42-67; col. 6, ll. 1-12) and serves as the lubricant, and a target compound, which is placed on the intermediate layer (or lubricant) and is a fluorescent group (col. 3: ll. 12-14, 22-24; col. 9, ll. 4, 62-63; "fluorescein"). The target compound is photo-immobilized on top of the intermediate layer and forms a fluorescent lubricant. Anderson et al. further disclose applying the fluorescent lubricant to a surface of a medical device to form a coating capable of exhibiting fluorescence (col. 10). Anderson et al. disclose subjecting

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fluorescein and the lubricant to external energy so that fluorescein covalently bonds to the lubricant, and this external energy may induce fluorescence from fluorescein (col. 7, ll. 37-44)

Regarding claims 17 and 18, Anderson et al. disclose a medical device being an intraluminal medical device and a catheter (col. 10, ll. 56-65).

Regarding claim 31, Anderson et al. disclose a medical device comprising a single coating (col. 10, ll. 56-67). Anderson et al. disclose an intermediate layer, which is “abrasion resistant” (col. 5, ll. 42-67; col. 6, ll. 1-12) and serves as the lubricant, and a target compound, such as fluorescein (col. 9, ll. 63-64), which is photo-immobilized onto the intermediate layer (col. 3, ll. 12-14, 22-24; col. 9, ll. 4, 62-63). The target compound is photo-immobilized or covalently bonded to the intermediate layer, forming a single coating that comprises a mixture of at least one lubricious compound and at least one fluorescing agent.

Regarding claims 16, 32, 33, Anderson et al. disclose a lubricious coating for use on a medical device (col. 3, ll. 50-54; col. 10, ll. 56-65). The coating comprises a mixture of at least one hydrophobic lubricant, at least one hydrophilic fluorescent dye, and at least one surfactant. Anderson et al. disclose an intermediate layer, which is “abrasion resistant” (col. 5, ll. 42-67; col. 6, ll. 1-12) and serves as the lubricant. The intermediate layer or lubricant includes silicone containing polymers, which are hydrophobic. Anderson et al. further disclose the target compound, which is photo-immobilized on the intermediate layer (or lubricant) and can consist of fluorescein, which is hydrophilic. Anderson et al. also disclose a surfactant (coupling compound) that helps attach the hydrophobic silicone containing lubricant and the hydrophilic fluorescent dye, fluorescein (col. 3, ll. 26-38). Anderson et al. disclose that subjecting fluorescein (the fluorescent dye) and the lubricant to external energy causes fluorescein to

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covalently bond to the lubricant, and fluorescence from fluorescein may be induced (col. 7, ll. 37-44).

Regarding claim 34, Anderson et al. disclose the medical device (col. 3, ll. 50-54; col. 10, ll. 56-65) wherein the lubricious compound is silicone based (col. 5, ll. 41-42).

Regarding claim 35, Anderson et al. disclose the medical device (col. 3, ll. 50-54; col. 10, ll. 56-65) wherein the lubricious compound (intermediate layer) is polydimethylsiloxane (col. 5, ll. 41-42, 50).

Regarding claim 36, Anderson et al. disclose the medical device (col. 3, ll. 50-54; col. 10, ll. 56-65) wherein at least one fluorescing agent is fluorescein, rhodamine, triarylmethane, derivative thereof or mixture thereof (col. 9, ll. 63-64: "fluorescein").

Regarding claim 37, Anderson et al. disclose the medical device (col. 3, ll. 50-54; col. 10, ll. 56-65) wherein the at least one fluorescing agent is 5-carboxyfluorescein, indocyanine green, lissamine green, rose Bengal, or mixture thereof (col. 9, ll. 63-64 "fluorescein").

Regarding claim 38, Anderson et al. disclose a lubricious coating for use on medical devices (col. 3, ll. 50-54; col. 10, ll. 56-65) comprising a fluorescenated lubricant. Anderson et al. disclose an intermediate layer, which is "abrasion resistant" (col. 5, ll. 42-67; col. 6, ll. 1-12) and serves as the lubricant, and a target compound, which is placed on the intermediate layer (or lubricant) and is a fluorescent group (col. 3: ll. 12-14, 22-24; col. 9, ll. 4, 62-63). The target compound is photo-immobilized (covalently bonded) to the intermediate layer, and together they form a fluorescent lubricant.

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Claim Rejections - 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,254,634 B1 to Anderson et al.

Regarding claims 19, 20, 21, and 23, Anderson et al. disclose a method capable of determining the presence of a lubricious coating by adding at least one fluorescent agent (the target compound, fluorescein) to at least one lubricant (the intermediate layer). Fluorescein covalently bonds to the lubricant upon activation by an external energy source, and after subjecting fluorescein and the lubricant to external energy, fluorescence from fluorescein may be induced (col. 7, ll. 37-44). Anderson et al. further disclose a list of coatable devices, such as a catheter (col. 10, l. 58) and a stent, but however, do not disclose a stent delivery catheter, stent retaining sleeve, or coating the inner surface of the stent retaining sleeve. It is well known and obvious that the coat can be used on any type of commonly used catheter, such as a stent delivery catheter, which inherently would have a stent retaining sleeve. It is also obvious from Anderson et al. and well known to coat any portion of the catheter using the method of Anderson et al. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a stent delivery catheter with a stent retaining sleeve and to be capable of

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coating any portion of that catheter, such as the inner surface of the sleeve, since the method of Anderson et al. is applicable to many catheters and able to coat any portion of those catheters.

Regarding claim 22, Anderson et al. disclose the method comprising the step of observing the fluorescence to determine the presence, location, and uniformity of the lubricant. Anderson et al. disclose using fluorescein (col. 9, ll. 63-64; col. 1-5, 55-65), a fluorescent molecule to covalently bond to a lubricant (the intermediate layer). It is inherent that fluorescein is observable and can be used to detect the presence of the lubricant.

Regarding claim 24, Anderson et al. disclose the lubricious coating comprising either a hydrophilic lubricant or a hydrophobic lubricant (col. 5, ll. 41-64). The intermediate layer serves as the lubricant and consists of silicone containing polymers. Silicone is hydrophobic.

Regarding claims 25 and 26, Anderson et al. disclose the lubricious lubricant being polydimethylsiloxane and a cross-linkable material (col. 5, ll. 41-64).

Regarding claim 27, Anderson et al. disclose the fluorescent dye being hydrophilic. The hydrophilic dye is fluorescein, and fluorescein is hydrophilic (col. 9, ll. 62-64).

Regarding claims 28 and 29, Anderson et al. disclose a fluorescing agent being fluorescein, rhodamine, triarylmethane, derivative thereof, or mixture thereof (col. 9, ll. 62-64).

Regarding claim 30, Anderson et al. disclose the lubricant being a hydrogel ("hydride terminated polydimethylsiloxane"; col. 6, ll. 2-23).

Allowable Subject Matter

Claims 1 and 3-14 are allowable. Regarding claim 1, the cited prior art fails to teach composing a mixture of at least one fluorescing agent and at least one lubricant and *then* applying the *mixture* to the surface of the medical device. The prior art discloses a lubricant

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applied to a medical device and then the fluorescing compound applied to the lubricant. Claims 3-14 depend from claim 1, and hence are also allowable.

Response to Arguments

Applicant's arguments filed 1/31/03 have been fully considered but they are not persuasive. Anderson et al. disclose a lubricant to which a fluorescent compound is attached (covalently bonded) through photo-immobilization. This allows the areas of the lubricant on which the fluorescent compound is attached to fluoresce.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijsphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP

April 2, 2003

GP

Gwen Phanijphand
Patent Examiner
Art Unit 3731



Michael J. Milano
Supervisory Patent Examiner
Technology Center 3700